K012798
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SUMMARY OF SAFETY AND EFFECTIVENESS

Sponsor: Biomet, Inc.
P.O. Box 587
Warsaw, IN 46581-0587

Contact Person: Dalene T. Binkley
(800) 348-9500, ext. 1612

Device Name: Intex Screw

Classification Name: screw, fixation, bone fastener (21 CFR 888.3040)

Device Product Code: 87 HWC

Indications for Use: The Intex Screw is to be for fixation of bone fractures and for bone reconstruction (i.e. fresh fractures, osteotomy, revision procedure where other treatments or devices have failed, arthrodesis, and in conjunction with fixation hardware).

Device Description: The Intex Screw is an internal fixation device intended to aid in the alignment and stabilization of fractures in the skeletal system until healing has occurred.

The Intex Screw consists of an internal cannulated screw and an external stud joined at a junction. After inserting the device, the external stud is held in place by an external fixator to allow for healing. When the surgeon feels that external fixation is no longer needed, the external stud is removed, leaving the internal cannulated screw. This design allows the surgeon to maintain internal fixation after the external fixation device is removed.

Potential Risks: The potential risks associated with this device are the same as with any joint replacement device. These include, but are not limited to:

Reaction to bone cement	Blood vessel damage	Bone fracture
Deformity of the joint	Soft tissue imbalance	Infection
Cardiovascular disease	Delayed wound healing	Hematoma
Fracture of the cement	Metal sensitivity	Dislocation
Implant loosening/migration	Fracture of the components	Excessive wear
Tissue growth failure	Nerve damage	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 16 2001

Ms. Dalene T. Binkley
Regulatory Specialist
Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581

Re: K012798
Trade/Device Name: Intex™ Screw
Regulation Number: 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: August 20, 2001
Received: August 21, 2001

Dear Ms. Binkley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510 (k) NUMBER (IF KNOWN): K012798

DEVICE NAME: Intex™ Screw

INDICATIONS FOR USE:

The Intex Screw is indicated for fixation of bone fractures and for bone reconstruction (i.e. fresh fractures, osteotomy, revision procedure where other treatments or devices have failed, arthrodesis, and in conjunction with fixation hardware).

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter-Use____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

for Mark N Milla

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012798